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10/820,848	04/09/2004	Lawrence V. Tannenbaum	CHPPM 03-22 03	8673

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OFFICE OF THE STAFF JUDGE ADVOCATE
U.S. ARMY MEDICAL RESEARCH AND MATERIEL COMMAND
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EXAMINER

LIN, JERRY

ART UNIT	PAPER NUMBER
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1631

MAIL DATE	DELIVERY MODE
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07/23/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/820,848

Applicant(s)

TANNENBAUM, LAWRENCE V.

Examiner

Jerry Lin

Art Unit

1631

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 May 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) 7-12, 14 and 17 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6, 13, 15, 16, 18-21 is/are rejected.
- 7) ☒ Claim(s) 19-21 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 2/23/2007.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election of Species F (claim 15) in the reply filed on May 15, 2007 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

2. Claim 17 is drawn to the invention of species D, which was previously withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on October 10, 2006.

Claim 14 is withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on May 15, 2007.

3. Applicants' arguments, filed February 26, 2007, have been fully considered and they are not deemed to be persuasive. The following rejections and/or objections are either reiterated or newly applied as necessitated by amendment. They constitute the complete set presently being applied to the instant application.

Status of the Claims

Claims 1-6, 13, 15, 16, and 18-21 are under examination.

Claims 7-12, 14, and 17 are withdrawn as being drawn to a non-elected invention or species.

Claim Objections

4. Claims 19-21 are objected to because of the following informalities:
“compromised” is spelled as “comprised”. Appropriate correction is required.

Claim Rejections - 35 USC § 112, 1st Paragraph

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claim 1-6, 13, 15, 16, and 18-21 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for determining the ecological risk to mice, does not reasonably provide enablement for determining the ecological risk to other animals. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims.

The instant claims are drawn to a method of assessing ecological risk for animals by performing sperm analysis on rodents from a contaminated site and a

Art Unit: 1631

reference site and comparing the results of the rodents from the different sites, where if the results exceeds a benchmark, the rodents have impaired reproductive capability and assessing the ecological risk to animals at the contaminated site.

The preamble and the final step of the independent claims, claims 1, 13 and 18, recite that the method assesses the ecological risk to animals. Giving the word "animals" a broad reading, the claimed method determines the ecological risk to animals other than rodents. However, the method only examines data derived from rodents. While it is clear that there the claimed method may measure the ecological risk to rodents, the method may not measure the ecological risk to other animals. According to Tannenbaum et al. (Applicant's IDS reference # 5), this method makes the assumption that, "small rodents at a contaminated site are deemed to have impaired reproductive capability on the basis of less quality sperm parameters, by implication, other site terrestrial receptors have the potential to be experiencing similar reduced reproductive success. This is a conservative assumption, because the degree of direct soil contact in wider-ranger mammals and birds (e.g., deer and hawks) is substantially less than that of small ranging small rodents. . . ." (page 22, left column). In addition, Tannenbaum et al., goes on to state that other rodents may be unsuitable for this method (page 26, right column, last full paragraph). The instant specification does not provide any data or rationale of why determining the ecological risk to mice may be extrapolated to assess the ecological risk to

Art Unit: 1631

other animals. Thus in order to determine the ecological risk to other animals, one of ordinary skill in the art must perform undue experimentation.

Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized in Ex parte Forman, 230 USPQ 546 (BPAI 1986) and reiterated by the Court of Appeals in In re Wands, 8 USPQ2d 1400 at 1404 (CAFC 1988). The factors to be considered in determining whether undue experimentation is required include:

- (1) the quantity of experimentation necessary – since it is unknown whether the ecological risk to mice may be extrapolated to other animals, a great deal of experimentation is needed.
- (2) the amount of direction presented – the specification focuses on mice, but does derive data from other animals or teach how the data from mice applies to other animals.
- (3) the presence or absence of working examples – there are no working examples of data from animals other than rodents.
- (4) the nature of the invention – the invention is drawn to assessing how animals will react to a contaminated site. How an organism will react to environmental changes is unpredictable.
- (5) the state of the prior art – the prior art does not show how the data from mice may be extrapolated to other animals. Thus, Tannenbaum et al. makes the assumption that it may apply to other animals.
- (6) the relative skill of those in the art – the level of skill in the biological sciences is high.

Art Unit: 1631

(7) the predictability or unpredictability of the art - the Board also stated that although the level of skill in the biological sciences is high, the results of experiments in biological sciences are unpredictable.

(8) the breadth of the claims – the instant claims are drawn to assessing the ecological risk to animals.

Given the analysis and consideration of the factors above, one of ordinary skill in the art would have to perform undue experimentation in order to practice the claimed invention commensurate in scope with these claims.

This rejection was necessitated by amendment.

7. Claim 16 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a New Matter rejection.

Newly submitted claim 16 recites that the rodents from the contaminated site reflect one hundred generations of exposure. However, the specification, as filed, makes no mention of the number of generations of rodents that are exposed to a contaminated site or use a number of generations of rodents for performing the method of claim 1. Since the subject matter of claim 16 was not present in the originally filed application, the subject matter of claim 16 is New Matter.

This rejection was necessitated by amendment.

Claim Rejections - 35 USC § 112, 2nd Paragraph

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claim 1-6, 13, 15, 16, and 18-21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1, 13 and 18 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: how the newly added step (f) in claims 1 and 13, and the last step in claim 18 related to the prior comparing step. Step (e) compares the results obtained from steps (c) and (d), but step (f) only uses the result of step (c). In other words, it is not clear what and how step (d) and (e) contribute to assessing ecological risks to animals. Furthermore, since both the preamble and step (f) generically refer to ecological risk to animals, it is unclear whether other animals, in addition to rodents as recited in steps (a)-(e), are required to be analyzed.

Claim 13 has been amended to recite the limitation of "former burning ground sites" in step (a). However, it is unclear what criteria must be met for a ground site to be a burning ground site. The specification does not define the term, nor does a search of the prior art reveal any commonly accepted definition of the term. Furthermore, the metes and bounds of "former" are unclear because

Art Unit: 1631

it is not clear to what, when, and where "former" is referenced. Clarification via clearer claim language is requested.

This rejection was necessitated by amendment.

Claim Rejections - 35 USC § 102

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this

Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

11. Claims 1, 2, 3, and 6 are rejected under 35 U.S.C. 102(b) as being anticipated by Ieradi et al. (Environmental Pollution (1996) Volume 92, number 3, pages 323-328).

The instant claims are drawn to a method for assessing the risk to animals by obtaining mice from a contaminated site and a reference site, performing sperm analysis on the mice, comparing the sperm analysis of the mice from the reference site to the sperm analysis of the mice from the contaminated site, and determining if the results from the first sperm analysis exceeds one or more sperm parameter benchmarks.

Regarding claims 1, 2, 3, and 6, Ieradi et al. teach a method for determining the ecological risk to animals by obtaining a sample of mice from a contaminated site (page 324, left column); obtaining mice from a reference site

Art Unit: 1631

(control group) (page 324, left column); performing sperm analysis on all the mice (page 324, left column); comparing the results of the mice (where the data from the control group is a benchmark for indicating impaired reproductive capability) (page 324, left column; page 325, figure 1; page 326, left column).

Response to Arguments

12. The Applicants have responded to this rejection by stating that leradi et al. does not teach if the sperm analysis exceeds one or more sperm benchmarks. However, leradi et al. teach comparing the results of the mice from the contaminated site to the mice from the reference site. The data from the mice from the reference site may be viewed as the "benchmark" for determining the impaired reproductive capability of the mice. Thus the instant reference teaches the amended limitation.

This rejection is maintained from the previous office action and modified as necessitated by amendment.

Claim Rejections - 35 USC § 103

13. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Art Unit: 1631

14. Claims 4, 5, 13 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ieradi et al. (Environmental Pollution (1996) Volume 92, number 3, pages 323-328) as applied to claims 1-3 and 6 above, and further in view of Sharma et al. (Reproductive Toxicology (1996) Volume 10, number 2, pages 153-159).

The instant claims are drawn to a method for assessing the risk to animals by obtaining rodents from two former burning ground sites based on hazard quotients; obtaining animals from reference sites; removing the vas deferens from rodents to assess sperm motility; removing the epididymis from the rodents to assess sperm count and sperm abnormality; removing the epididymis from the rodents to assess sperm morphology; and comparing the results from the rodents from the different sites. For purposes of this Examination, the term "burning ground sites" is interpreted to mean a contaminated site.

Regarding claims 1, 13, and 18, Ieradi et al. teach a method for determining the ecological risk to animals by obtaining a sample of mice from two contaminated sites with high hazard quotients (page 324, left column); obtaining mice from a reference site (control group) (page 324, left column); assessing sperm abnormality and morphology by obtaining a sample from the epididymis (page 324, left column; page 325, figure 1; page 326, left column); comparing the results of the mice (where the data from the control group is a benchmark for indicating impaired reproductive capability) (page 324, left column; page 325, figure 1; page 326, left column).

However, leradi et al. does not teach removing the vas deferens to assess sperm motility or assessing sperm count.

Regarding claims 4, 5, 13, and 18, Sharma et al. teach a method of determining the toxicity of a chemical in mice by removing the vas deferens and epididymis to assess sperm count and motility (abstract; page 156).

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the methods of leradi et al. and Sharma et al. leradi et al. and Sharma et al. are both concerned with the effects of environmental pollution on human and animal systems (abstract of both). In particular they are concerned with metals such as lead or mercury (abstract of both). leradi et al. states that wild rodents are useful as bioindicators to detect local contamination (page 327, right column). Given that Sharma et al. are concerned with determining that toxic effects of mercury in animal systems (pate 153, left column), one of ordinary skill in the art would have sought to use a known bioindicator to detect the local contamination of mercury at a particular site. Thus one of ordinary skill in the art would have been motivated to combine the methods of leradi et al. and Sharma et al. to trap wild mice and conduct the sperm analysis suggested by leradi et al. and Sharma et al. to determine the pollution at a site.

Art Unit: 1631

Response to Arguments

15. The Applicants have responded to this rejection by stating that leradi et al. and Sharma et al. do not teach sperm parameter benchmarks of impaired reproductive capability. Please see above for the Examiner's response.

This rejection is maintained from the previous office action and modified as necessitated by amendment.

16. Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over leradi et al. (Environmental Pollution (1996) Volume 92, number 3, pages 323-328) in view of Sharma et al. (Reproductive Toxicology (1996) Volume 10, number 2, pages 153-159) as applied to claims 1-6, 13 and 18 above, and further in view of Phillips et al. (Federal Facilities Environmental Journal (2002) Volume 13, Issue 1, pages 7-25).

leradi et al. and Sharma et al. are applied as above.

However, neither leradi et al. nor Sharma et al. teach that a contaminated site may be contaminated with explosives.

Phillips et al. teach collecting rodents from a contaminated site that may be contaminated with explosives (page 13, bottom).

It would have been obvious for one of ordinary skill in the art at the time of the invention to collect rodents from a contaminated site with explosives, such as Phillips et al., and to use the methods of leradi et al. and Sharma et al. to determine the effects of contamination by explosives on mice. leradi et al., Sharma et al., and Phillips et al. are all concerned with the effects of

Art Unit: 1631

environmental pollution on human and animal systems (abstract of each reference). Phillips et al. teaches that analyzing the ecological risk to humans and animals at sites contaminated with explosives is desirable to identify potential hazards (abstract). Ieradi et al. teach that their method helps determine the environmental effects on a rodent (abstract). Thus, one of ordinary skill in the art would have been motivated to use the rodents from the sites disclosed by Phillips et al. and apply the methods of Ieradi et al. and Sharma et al. to determine the human and ecological risks at these contaminated sites.

This rejection is necessitated by amendment.

17. Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ieradi et al. (Environmental Pollution (1996) Volume 92, number 3, pages 323-328) in view of Sharma et al. (Reproductive Toxicology (1996) Volume 10, number 2, pages 153-159) as applied to claim 18 above, and further in view of Meistrich et al. (Applicant's IDS #4).

Ieradi et al. and Sharma et al. are applied as above.

However, neither Ieradi et al. nor Sharma et al. teach that an 80% to 90% decrease in sperm count indicates compromised reproductive success.

Meistrich et al. teach that an 80% to 90% decrease in sperm count indicates compromised reproductive success (page 75, left column, 2nd full paragraph).

It would have been obvious for one of ordinary skill in the art at the time of the invention to use the criteria of Meistrich et al. with the methods of Ieradi et al.

Art Unit: 1631

and Sharma et al. to determine the effects of pollution on mice. Ieradi et al. and Sharma et al. are both concerned with the effects of environmental pollution on human and animal systems (abstract of both). Environmental pollution often affects an animal's ability to reproduce. Thus one of ordinary skill in the art would be motivated to use the criteria of Meistrich et al. in order to determine if the rodents obtained by Ieradi et al. had a compromised reproductive system because of sperm count.

This rejection is necessitated by amendment.

18. Claims 20 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ieradi et al. (Environmental Pollution (1996) Volume 92, number 3, pages 323-328) in view of Sharma et al. (Reproductive Toxicology (1996) Volume 10, number 2, pages 153-159) as applied to claim 18 above, and further in view of Chapin et al. (Applicant's IDS #2).

Ieradi et al. and Sharma et al. are applied as above.

However, neither Ieradi et al. nor Sharma et al. teach that a decrease of about 40%-50% in sperm motility or an increase of 4% or more of abnormally shaped sperm indicates compromised reproductive success.

Chapin et al. that a decrease of about 40%-50% in sperm motility or an increase of 4% or more of abnormally shaped sperm indicates compromised reproductive success (abstract; page 131, left column, bottom; page 131, right column, 2nd full paragraph).

Art Unit: 1631

It would have been obvious for one of ordinary skill in the art at the time of the invention to use the criteria of Chapin et al. with the methods of leradi et al. and Sharma et al. to determine the effects of pollution on mice. leradi et al. and Sharma et al. are both concerned with the effects of environmental pollution on human and animal systems (abstract of both). Environmental pollution often affects an animal's ability to reproduce. Thus one of ordinary skill in the art would be motivated to used the criteria of Chapin et al. in order to determine if the rodents obtained by leradi et al. had a compromised reproductive system because of sperm motility or abnormally shaped sperm.

This rejection is necessitated by amendment.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory

Art Unit: 1631

action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jerry Lin whose telephone number is (571) 272-2561. The examiner can normally be reached on 10:00-6:30, M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571) 272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1631

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/JL/

/Shubo (Joe) Zhou/

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PRIMARY EXAMINER